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Executive Office of Health and Human Services
Department of Public Health
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Circular Letter: DHCQ 14-6-617

TO: Chief Executive Officers, Acute Care Hospitals

FROM: Madeleine Biondolillo, MD
Associate Commissioner

Deborah Allwes, BS, BSN, MPH
Director, Bureau of Health Care Safety and Quality

DATE: July 14, 2014

RE: Policy Updates for Cardiac Catheterization Services

The purpose of this Circular Letter is to inform you of updated policies related to the provision of hospital-based cardiac catheterization services licensed by the Department of Public Health (the Department or DPH) pursuant to 105 CMR 130.900-.982. The three issues addressed in this document are:

1. Clarification of requirement to meet volume minimums for cardiac catheterization services;
2. Amended policy applicable only to certain Accountable Care Organizations (ACOs) regarding the moratorium on new cardiac catheterization services; and
3. New policy regarding percutaneous coronary intervention (PCI) services.

Clarification of requirement to meet volume minimums for cardiac catheterization services:

Hospitals must meet the facility and operator volume minimums set forth in the DPH hospital licensure regulations. These minimums include:

1. For a hospital performing only diagnostic procedures - 300 diagnostic procedures per year.
2. For hospitals performing both diagnostic and therapeutic (interventional) procedures - 600 procedures per year, of which at least 200 are percutaneous coronary interventions (PCIs).

3. For interventionalists, current minimum is 75 PCI procedures per year. However, consistent with current national guidelines supported by the Department's Invasive Cardiac Services Advisory Committee (ICSAC), the Department plans to revise the regulation to reflect a minimum of 50 per year (averaged over two years).

If a hospital has not met, or does not meet, for two years in a row, the DPH volume minimums -- in addition to meeting quality assurance as described in 105 CMR 130.965: In-house Evaluation of Quality -- the hospital must develop a plan, for approval by DPH, to meet the volume minimums within one year. If the hospital does not submit a plan that is accepted by the Department, the hospital may be required to cease performing cardiac catheterization procedures within thirty days of receipt of notice from the Department that either the plan is not accepted, or that the Department did not receive a plan as required. Any hospital that has not met the volume minimums for the past two years should submit by September 30, 2014 its plan to meet the volume minimums within one year to: the Hospital Complaint Unit Manager at the Bureau of Health Care Safety and Quality, at Debbie.Ulin@state.ma.us. For future instances of non-compliance with the volume minimums, the plan should be submitted within 90 days of the hospital's identification of non-compliance.

Accountable Care Organization Proposals for a New Cardiac Catheterization Service:

The moratorium on establishment of a new cardiac catheterization service within 30 minutes of an existing percutaneous coronary intervention (PCI)-capable hospital remains in effect, **except under the following limited circumstances.**

1. A hospital that proposes a new cardiac catheterization service within the geographic limitation set by the moratorium is part of a health care system recognized as a Pioneer ACO, a Medicare Shared Savings Plan ACO, or other ACO designation to be determined by the Department; the hospital system has an existing cardiac catheterization service at another hospital within its system that does not meet the minimum diagnostic volume (300 procedures); and the hospital system is proposing to transfer the existing service license to establish a new diagnostic cardiac catheterization service at another hospital in the same ACO system.
2. The ACO will document, to the Department's satisfaction, the projected volume of diagnostic cardiac catheterization procedures at the proposed new site and the underlying assumptions associated with the volume projection, including:
 - a. where the patient population the ACO assumes it would treat at the new site is currently receiving diagnostic cardiac catheterization procedures; and
 - b. how the ACO anticipates ensuring these patients will use the service at the new diagnostic cardiac catheterization site.
3. The hospital agrees to supply the Department with its diagnostic cardiac catheterization procedure volume data on a quarterly basis for the first twenty-four months of operation of the new cardiac catheterization service. After that period, consistent with the DPH hospital licensure regulation, if the hospital has not met the regulatory volume minimum, the hospital shall submit to the Hospital Complaint Unit Manager at the Bureau of Health Care Safety

and Quality, its quarterly quality assessment and performance improvement (QAPI) program report findings, recommended actions, progress on implementation and supporting data, as described in 105 CMR 130.965: In-house Evaluation of Quality. The hospital will continue to submit these reports until the hospital receives a notice from the Department to discontinue submission of the reports.

4. If a hospital receives approval from DPH for a transfer as proposed in #1 above, the transfer of the existing cardiac catheterization service failing to meet the minimum volume requirement shall occur within sixty days after notice of an approval to create a new cardiac catheterization service at the hospital seeking the new service as a condition of the approval, and prior to licensure of the cardiac catheterization service at the new site.

An eligible ACO should submit to the Department a letter of intent to transfer the location of a cardiac catheterization service from one hospital license to another within its ACO. The letter shall describe which hospital will close its cardiac catheterization service and which will open a proposed new cardiac catheterization service. The letter will include the information described in #2, above. It must also include language acknowledging that the ACO will submit:

- a. **a plan to address any other facility within the ACO that is not meeting the current volume minimums under licensure, as summarized in “Clarification of requirement to meet volume minimums for cardiac catheterization services” above;** and
- b. the information required in #3 above.

The letter should be sent to the Director, Bureau of Health Care Safety and Quality, at Deborah.Allwes@state.ma.us. Upon written approval by the Department, the hospital may proceed with the Department’s architectural plan review process for the new cardiac catheterization service.

Such approval of a new diagnostic cardiac catheterization service under the above terms in no way guarantees that service will be approved in the future, through any separate DPH process, to provide emergency or non-emergency angioplasty at that site.

New Percutaneous Coronary Intervention Services:

At its meeting on April 17, 2014, based on the recommendation of its PCI Oversight Subcommittee, the Department’s ICSAC voted to recommend to the Department that upon consideration of several factors, including the declining PCI volume in Massachusetts and that at least eighty-six percent of the population lives within a 30-minute ambulance ride of a PCI-capable hospital, there is no demonstrable need for any additional emergency or non-emergency PCI programs in the Commonwealth and that any additional programs may have an adverse impact on the existing quality of PCIs performed¹.

The ICSAC further recommended that if there are changes to the current state of PCI volume or services in Massachusetts, new emergency or non-emergency PCI programs should be

¹ An application for primary PCI that was filed before April 17, 2014 is pending Department action.

considered solely on the basis of evaluating a patient-based need assessment for PCI services through a comprehensive review of:

- a. Geographic need for PCI services, through a demonstration of a lack of availability of emergency PCI services within a 30-minute ambulance drive from the proposed facility and a facility that currently provides this service;
- b. A detailed program proposal to DPH that would assure quality and safety of the PCI procedures performed at the proposed center; and
- c. An impact assessment, to be performed by DPH and in conjunction with the ICSAC, to assess the potential impact of any new PCI program on existing PCI programs in Massachusetts in terms of quality, safety and procedural volumes.

The Department has adopted the ICSAC's recommendations and therefore these terms are in effect.

Questions about this letter should be directed to: Nancy Murphy at Nancy.Murphy2@massmail.state.ma.us